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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,664	01/22/2004	David J. Beebe	282.033	5152
23598	7590	10/22/2007		
BOYLE FREDRICKSON S.C. 840 North Plankinton Avenue MILWAUKEE, WI 53203			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
			NOTIFICATION DATE 10/22/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@boylefred.com

## Office Action Summary

Application No.

10/762,664

Applicant(s)

BEEBE ET AL.

Examiner

Andrew M. Gilbert

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9, 17 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) 9, 17, 20 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21 is/are rejected.
- 7) ☒ Claim(s) 22-24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Acknowledgments***

1. This office action is in response to the reply filed on 8/2/2007.
2. In the reply, the Applicant cancelled claims 1-8, 10-16 and 18. Claims 9, 17, 20, and 25 remain withdrawn.
3. Claims 21-24 were indicated as allowable in the previous office action. That indication has been rescinded in view of the rejections discussed below.
4. Thus, claims 21-24 remain pending:

### ***Claim Objections***

5. Claim 21 objected to because of the following informalities: Claim 21 lacks a period at the end of the claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kriesel et al (6416495) in view of Kriesel et al (5693018). Kriesel et al '495 discloses a microfluidic device (Fig 4) for delivering a drug to an individual, comprising: a body (24) defining a reservoir (44) for receiving the drug; an output cannula (137) having an input in communication with the reservoir (Fig 4) and an output receivable within the individual (Fig 3, 4, Summary); a pressure source (70) including an hydrogel member (70) expandable in response to exposure to a

Art Unit: 3767

predetermined physical property (col 6, lns 33-47, col 10, lns 9-21), the hydrogel member engageable with the reservoir and urging the drug from the reservoir through the output cannula as the hydrogel member expands (Fig 4, Summary, col 5, lns 15-col 6, lns 1, col 6, lns 33-47, col 10, lns 9-21); and a valve (64) defining a chamber and interconnecting the reservoir and the output cannula (Fig 4), the valve movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle (64, Fig 4, Summary, col 5, lns 15-col 6, lns 1, col 6, lns 33-47, col 10, lns 9-21) .

8. However, Kriesel et al '495 does not expressly disclose that the output cannula is a needle and that the device has an adhesive for affixing the body to the individual.

9. Kriesel et al '018 teaches that it is known to have the output cannula is a needle (26b) and that the device has an adhesive (layer "A") for affixing the body to the individual for the purpose of providing a subdermal insulin delivery device that is attached to the patient's skin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the output cannula and device as taught by Kriesel et al '495 with the output needle and adhesive securement as taught by Kriesel et al '018 for the purpose of a subdermal insulin delivery device that is attached to the patient's skin.

***Allowable Subject Matter***

10. Claims 22-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3767

***Response to Arguments***

11. Applicant's arguments with respect to claims 21-24 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

